

K193177 CER-SAug 26, 2020
282 days to decisionK193177 · Product code: **MLO** · CardiovascularSource: <https://www.510kdatabase.net/k193177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Nov 18, 2019
Decision date	Aug 26, 2020
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardiocalm
Location	Montichiari, IT
Contact	Fabio Badilini
510(k) history	1 submissions · 1 cleared · 2020-2020

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